Enhancing flexibility, minimizing risk

As a startup CMO grew to become a leader in gene therapy, our containment solutions helped them scale up

Situation

A decade ago, a small contract manufacturing organization (CMO) was just getting started. They began in a small leased lab space with a small bioreactor at a major private research institution. They got off the ground doing plasma production and development work on a small scale for a few gene therapy customers. At the time, exploring the potential therapeutic uses of genes was a relatively new area of scientific research, and there wasn't yet a large demand for what the company offered. But they were ahead of the curve; they anticipated the boom in gene therapy research that was just around the corner. In just a few years, they were expanding from that little incubator space into an operation requiring an entire floor of the University of Maryland BioPark building, and then another floor—and eventually they built their own 200,000 square foot facility for large-scale manufacturing.

Thermo Fisher Scientific partnered with and supported the company from the beginning. At first, the limits of business and budget meant the company's product needs were also modest: from Thermo Fisher, they purchased some media and other consumables for small-scale research and development. They also purchased products, including biocontainers, from other manufacturers.

But with expanded business came new challenges. One of them was a time-sensitive need for a sterilized carboy with a custom-made cap to accommodate a dip tube that could support their increasing volume and flow-rate demands. Thermo Fisher was able to meet that challenge with a quick turnaround on a custom-designed, high-quality Thermo Scientific™ Nalgene™ container. This positive experience encouraged the company to discuss with Thermo Fisher a range of other issues and challenges they faced as they grew.

Nalgene rigid containment solutions

Solutions

After customizing the Nalgene carboy, Thermo Fisher was further consulted about the company's additional scale-up needs. To provide them with a comprehensive, hands-on experience of a variety of potential solutions, Thermo Fisher organized a Technology Day at the company's BioPark facility. Several Thermo Fisher representatives were there on-site, including a technical sales specialist for single-use technologies and a biosciences representative. In a large conference room, Thermo Fisher presented the Nalgene tiered portfolio of containment solutions, including production bottles, carboys, and a range of additional high-quality products for upstream and downstream bioproduction.

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At the Technology Day event, not only were the Thermo Fisher representatives able to share technical presentations centered around how the solutions they brought could meet the demands of the company's workflows, but many of the end users who had come out of the labs to check out the products were able to provide more direct information to the reps about their daily needs and challenges at the bench.

> "Process development depends heavily on a variety of Nalgene products, from PETG bottles to rapid-flow filtration units. The quality, reliability, and ease of use of these products allows us to efficiently deliver to our clients."
>
> —Sr. Laboratory Manager, Process Development

The biggest issue was that some of the products from other manufacturers that they had been using had quality issues, including cracking during the production process. It had caused interruptions in their process, and they were eager to hear about options for a potential switch. Already familiar with the high quality of the Nalgene carboy solution, some of the lab scientists were interested to learn that the durable polycarbonate material used in the carboy was also available in production bottles.

Another major concern for them was product contact. Bioproduction manufacturing requires consistency of product contact with the container materials throughout the process. This is a major advantage of the Nalgene rigid solutions line: as a business scales, the products scale with them, so that product contact with a 5 L biocontainer will be identical to product contact with a 50 L biocontainer. The company's scientists were impressed with the scalability potential of the Nalgene portfolio's wide variety of sizes available in the same material. In fact, this consistency of materials across container size extends to all three types of clean container material in the tiered portfolio—Standard, Certified, and Platinum Certified—each formulated and constructed to meet a different level of clean.

An additional advantage to Nalgene containers that helped convince them to make the switch is that the products meet every certification and compliance requirement of USP <788>. The rigid solutions are non-cytotoxic and non-pyrogenic, and each product comes with a validation binder that includes data to submit to a regulatory agency if necessary.

Results

After Technology Day, there was one more factor that influenced the company to make the switch: they wanted to try the products out, to see if there really was a difference. Thermo Fisher quickly arranged to make samples available.

And the samples sealed the deal.

The Thermo Fisher sales representative for the account explains, "Once they were able to use them in the lab, hands on, that's when the product sold itself. The quality is very good, and it definitely worked for what they needed. The material is very strong, so they could see it wasn't going to crack or degrade. As they sampled more of the products, their orders increased. And even this year, they're continuing to place orders for them."

Thus, it was the benefits of Nalgene rigid containment solutions—reliable quality, scalability, and compliance—combined with the opportunity to try them out in their lab, that influenced the company to make the switch that has reinforced a strong and ongoing relationship.

Learn more about Nalgene rigid containment tiered portfolio solutions at **thermofisher.com/uspclean**

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